



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Southwest Region

Food and Drug Administration  
Denver District Office  
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Denver, Colorado 80225-0087  
Telephone: 303-236-3000  
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October 7, 2002

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. J. Albin Smith  
Owner  
SAS Dairy  
506 SR 467  
Clovis, NM 88101

Ref. #: DEN-03-01

Dear Mr. Smith:

Consumer Safety Officer Michael L. Zimmerman conducted an inspection at your dairy farm on July 15-17, 2002. The inspection confirmed that you offered animals for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, you sold dairy cows on three separate occasions to X X X X X X X X X which were found to contain illegal levels of drug residues by USDA testing.

These four incidents, recorded under USDA case No. 01-1240-NM, include:

**July 26, 2001:** USDA analysis of tissue samples collected from your dairy cow with ear tag X X (USDA Sample No. 418024) identified the presence of Penicillin residue of 0.65 parts per million (ppm) in the kidney and 0.23 ppm in the liver. A tolerance of 0.05 ppm has been established for residues of Penicillin in the uncooked edible tissues of cattle in Title 21 Code of Federal Regulations, Part 556.510 (21 CFR 556.510).

**November 6, 2001:** USDA analysis of tissue samples collected from your dairy cow with ear tag No. X (USDA Sample No. 422327) identified the presence of Penicillin residue of 1.27 ppm in the kidney.

**April 25, 2002:** USDA analysis of tissue samples collected from your dairy cow with ear tag No. X (USDA Sample No. 439321) identified the presence of Penicillin residue of 0.79 ppm in the kidney; and the presence of Sulfadimethoxine residue of 4.40 ppm in the liver and 2.14 ppm in the muscle. USDA analysis of tissue samples collected from your dairy cow with ear tag No. 3 (USDA Sample No. 439323) identified the presence of Sulfadimethoxine residue of 6.62 ppm in the liver and 3.54 ppm in the muscle.

A tolerance of 0.1 ppm has been established for residues of Sulfadimethoxine in the uncooked edible tissues of cattle in 21 CFR 556.640.

Our investigation revealed the use of Penicillin G Procaine and Albon (Sulfadimethoxine). The presence of these drugs at the levels found in edible tissue from these animals causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under conditions that could allow medicated animals bearing potentially harmful drug residues to enter the food supply. For example, animal treatment records are inadequate or incomplete. In addition, you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. He may be reached at (303) 236-3054 if you have any questions about this matter.

Sincerely,



B. Belinda Collins  
District Director

cc: Dr. Ronald K. Jones  
D.V.M.  
Boulder District Manager  
USDA/FSIS  
665 S. Broadway, Suite B  
Boulder, CO 80303

